Evidence-Based Surgery

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Abstract Evidence-based surgery (EBS) involves the integration of the best clinical and scientific evidence to treat patients. Best evidence is derived from the research literature and can be categorised into a hierarchy of levels. Application of the knowledge derived from “best evidence” results in enhanced care for patients and also improved standards for surgeons and health care institutions. The sources of surgical evidence are discussed, and we review surgical training in evidence-based practice. Techniques for answering a surgical question using an evidence-based method and for practising surgery in an evidence-based environment are described. Furthermore, we examine the role of treatment networks, cost-effectiveness, evidence synthesis, surgical decision making and the ethics of EBS. For the current and future surgeon, evidence-based practice is now an inevitable and fundamental component of the surgical profession. Its universal adoption will play an important role in the advancement of patient care and surgery worldwide.

2.1 Introduction

Surgery has traditionally been considered a craft wherein individuals adopted techniques didactically from their teachers and performed each operation in a particular way because “that is how it was taught” to them. Throughout history, surgical practice has been dependent on learning through one’s own mistakes or those of others. Although a handful of exceptions did exist, such as the testing of medical efficacy by the eleventh century physician Avicenna [1], it was not until the late twentieth century that the concept of evidence-based medical practice came into fruition [2].

The concept of evidence-based practice involves the integration of the best available evidence to treat patients.
It has become an inevitability in surgery and is now a requirement of all modern health care institutions, surgeons and patients alike [3]. This chapter aims to clarify the role of evidence-based surgery (EBS) and to contextualise its part in current and future surgical practice. As Birch and colleagues [4] stipulated, “It is no longer acceptable for a surgeon to be estranged from the current literature – the demands of colleagues, licensing bodies, and patients necessitate satisfactory knowledge of the best available evidence for surgical care”.

### 2.2 What Is Evidence?

The Oxford English Dictionary defines Evidence as “information or signs indicating whether a belief or proposition is true or valid” [3]. As surgeons, we already apply this definition to our daily practice, so when we assess patients clinically, we all rely on our ability to draw clinical evidence from clinical signs and investigations, much in the same manner as Hippocrates did two and half thousand years ago.

The use of the word ‘Evidence’ in the context of evidence-base has a more specialised designation. EBS involves “the systematic, scientific and explicit use of current best evidence in making clinical decisions” [5].

### 2.3 Hierarchy of Evidence

The evidence used in EBS is derived from published scientific research. In order to allow for a comparative evaluation of research data, hierarchies of evidence have been developed, which rank evidence according to its validity. Initially randomised controlled trials (RCTs) were considered as providing the highest level of evidence as these were deemed to have more validity by decreasing research bias and analysis error when compared to single case reports and retrospective cohort reviews. More recently, however, the Centre for Evidence-Based Medicine at Oxford produced a hierarchy list of Evidence types (Fig. 2.1). Here, they classify non-experimental information at the lowest levels of evidence and randomised control trials at a much higher level. The highest level of evidence corresponds

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**Fig. 2.1** Hierarchy of evidence pyramid based on the levels advocated by the Oxford Centre for evidence-based medicine (May 2001) [6]
to evidence sources wherein data from multiple randomised trials are integrated and appraised in the form of meta-analyses and systematic reviews.

2.4 Definition and Values

The broad definition of EBS has been stipulated as “the integration of

- Best research evidence (clinically relevant research, basic science, relating to diagnosis, treatment and prognosis)

With

- Clinical expertise (skills and experience adapted to a particular patient) and patient values (patient preference and attitudes to clinical entity and its overall management)” [7].

This broad definition can then be divided into two subcategories [8]:

1. Evidence-based surgical decision making – in which best evidence is applied to an individual or a finite group of surgical patients.
2. Evidence-based surgical guidelines – in which best evidence is applied at an institutional or national/international group of surgical patients.

In order to apply best-evidence (Fig. 2.2), raw data need to be processed by a number of different types of knowledge. These include the following:

- Knowledge from research (refined data or evidence)
- Knowledge of measurement (statistical methodology)
- Knowledge from experience (judgments and decision)
- Knowledge of practice (leadership and management)

Thus, in order to carry out an evidence-based action, one needs to process raw clinical information by all the four knowledge types. An example would be a patient presenting with right iliac fossa pain and leucocytosis. As a clinician, one would use knowledge from research and experience to perform further investigations and make a provisional diagnosis. These data would be contextualised with data from the published literature and the knowledge of measurement. If a surgical indication such as the need for appendicectomy was deduced, the knowledge of leadership and management would need to be applied to ensure the progression to operative management.

2.5 Benefits of Evidence-Based Surgery

It has been predicted that “applying what we know already will have a bigger impact on health and disease than any drug or technology likely to be introduced in the next decade” [9]. The correct application of this knowledge is, therefore, critical in the development of future health care strategies and treatments. This has led to the concept that “Knowledge is the enemy of disease”, a metaphor that is both intuitive and has been increasingly applied by National Knowledge Service of the United Kingdom’s National Health Service [10]. Adopting a similar aim, the American College of Surgeons has also introduced the continuous quality improvement (CQI) [11] committee (initially known as the Office of Evidence-Based Surgery) [12], to promote the highest standards of surgical care through the evaluation of surgical outcomes in clinical practice.

There is, however, a large discrepancy between what we know and what we currently apply [9], and EBS is a method by which this discrepancy can be bridged, but also built upon to fundamentally improve surgical health care outcomes. Many so-called surgical standards and customs are based on little if no evidence. For example, the application of post-operative wound drains [8, 13] and nasogastric tubes [14] is largely determined by habit and surgical apprenticeship as opposed to best evidence.

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**Fig. 2.2** Application of knowledge in the process of transforming raw data into evidence-based action
Furthermore, part of the reason why such a gulf exists between knowledge and surgical application lies in the traditional philosophy of local and national health care policy. Here, the traditional *modus operandi* was defined by a practice that aimed to “minimise costs”, rather than actually address why we practice surgery in the first place, namely to benefit the patient. The future of health care, therefore, lies in the practice of a system that is built on the fundamental concept of value to patients (so called the “value-based” system). This model of health care can improve patient outcomes, quality of life, satisfaction and also financial cost [15]. At the heart of this value-based system is the practice of evidence-based surgery, which will enable care to be targeted for surgical diseases and patients as opposed to the “old fashioned” concept of treating patients by the “speciality” of their surgeons. Here, there will be a focus on risk-adjusted outcomes to improve patient care and satisfaction (Fig. 2.3).

Furthermore, such a system will allow the enhancement of surgical training (particularly in an era of decreased training hours), improve surgical satisfaction and empower surgeons through improved leadership, management and decision making (Fig. 2.3).

### 2.6 History and the So-Called “Discord” Between Surgery and Evidence-Based Practice

The historical perception that surgeons were unable to successfully apply evidence-based practice is not completely true. Many of the developments that led to its introduction in the twentieth century were spearheaded by surgeons. Working on the ideas of British physician Sir Thomas Percival (1740–1804), the American surgeon Ernest Codman (1869–1940) established the first tumour registry in the United States in order to follow-up patient outcomes, identifying the most successful aspects of tumour treatment. He was a notable health care reformer, and is credited for introducing outcomes management in patient care through an “end results system” by following-up patients and their outcomes, essentially creating the first patient health care database. He introduced the first mortality and morbidity meetings and contributed to the founding of the American College of Surgeons and its Hospital Standardization Program [16]. James Alison Glover (1930s UK) and later Jack Wennberg (1970s USA) revealed that mass adoption of tonsillectomies was unrelated to tonsillar disease occurrence, which lead to a change in surgical practice in keeping with actual disease rates [17]. The famed cardiovascular surgeon, Michael DeBakey reported on the overall surgical experience in World War II as he had been working for the Army Surgeon General’s Office. His work described injury incidence, surgical management and analysis of outcomes [18].

Although our modern concept of evidence-based medicine was first described by Scottish physician Archie Cochrane in 1972 [19], the formal adoption of “Best Evidence” occurred approximately 20 years later by Gordon Guyatt and David Sackett in the 1990s [2]. In the interim, however, some surgeons attempted to introduce evidence-based practice by publishing and acting on surgical outcomes through the Health Care Financing Administration (HCFA) [20].

Despite these significant contributions, surgeons have been criticised with statements such as “a large proportion of the surgical literature is of questionable value”, and that surgeons perform in a “comic opera” in

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**Fig. 2.3** Evidence-based surgery at the centre of a value-based health care system
which “they suppose are statistics of operations” [21]. These indictments to the surgical fraternity have come about as surgical research has historically relied upon publishing data that are deemed to be of the “weakest evidence”, based mainly on case series as opposed to randomised trials and meta-analyses. The root causes of these have been assessed in the literature [22]:

- Historical reasons (many operations progressed by small steps without RCTs).
- Patients do not want their operations to be selected by randomisation (patient’s equipoise).
- Operative variation makes standardisation of a surgical arm on an RCT difficult.
- Urgent and Emergency Surgery makes inclusion into an RCT difficult.
- The learning curve effect creates difficulty in analyzing RCTs.
- Many surgeons do not have an adequate grounding in medical statistics.
- Surgical RCTs have traditionally been poorly funded, whereas drug and technology companies have been more forthcoming in funding their device or procedure.
- Surgeons have traditionally been poor at adopting RCTs as they have surgical equipoise and self-assuredness – “my operation is better”.

The role of EBS is not to encourage a wider use of RCTs alone, but more importantly to arrive at surgical treatments that are considered “best evidence”. This does not always require an RCT and can include a wide corpus of other data that can be interpreted to select the best treatment for each patient.

### 2.7 Principles of Identifying the Evidence

In order to carry out EBS, four components need to be achieved, the so called “Four Steps of EBS” [7]:

Finding the best evidence is an essential skill for all modern surgeons. One well-applied method of performing a search is by utilising the “PICO” [5, 23] technique developed at McMaster University, where evidence-based methods have been taught for almost 30 years. Empirical studies demonstrate that PICO use improves the specificity and conceptual clarity of clinical problems, allows for more complex search strate-

1. Formulate a question based on a clinical situation encountered in daily practice.
2. Do a focused search of the relevant literature.
3. Critically appraise the literature obtained to find the best evidence.
4. Integrate the information and act in accordance with the best available evidence.

When asking a PICO question, it is important to:

- Be specific in your question(s)
- Prioritise your questions
- Ask answerable questions

A poor question would be:

“Is coronary artery bypass grafting better than angioplasty?”

A better question is:

“In diabetic Asian women aged over 75 with chronic stable angina and three vessel coronary artery disease, does off-pump coronary artery bypass grafting compare more favourably than percutaneous coronary intervention in terms of long-term mortality and physical quality of life?” This latter question can be derived from our PICO table:

The next step is to work through the finding evidence sequence (Fig. 2.4).

| P – patient | Asian women aged over 75 years with diabetes |
| I – intervention | Off-pump coronary artery bypass |
| C – comparison | Percutaneous coronary intervention |
| O – outcomes | Long-term mortality and Quality of Life |
2.8 Sources of Evidence

Sources of evidence can be selected from any of the categories of the “hierarchy of evidence” mentioned earlier. While traditionally these would have been discerned only from printed journal papers, many sources are now invariably available online through local intranets and the wider internet.

These sources (Fig. 2.5) can be categorised as primary sources or journal articles (which exist in large number) or secondary sources (which exist as a large variety). Primary sources provide direct evidence or data concerning a topic under investigation, whereas secondary sources summarise or add commentary to primary sources. As depicted in the figure, there is a hierarchy of secondary sources to match the hierarchy of evidence (Fig. 2.1). Thus, for example, textbooks are on the first run on the secondary sources pyramid, whereas the Cochrane Database of Systematic Reviews is at the peak of the source pyramid as it reveals information deemed to come from the highest level of evidence.

By far the most frequent database used by surgeons is PubMed [26], a free internet-based search engine for accessing the MEDLINE database of citations and abstracts of biomedical research articles. Here the vast majority of citations are from 1966 onwards, although they do reach back as far as 1951. PubMed is not the only search engine used, and many surgeons may start a search using Google Inc. search engines such as standard Google [27] or Google Scholar [28]. Alternatively, they may go straight to a government guideline website or even a systematic review database.

Fig. 2.4 Sequence of finding evidence in EBS based on McCulloch and Badenoch [24]

Fig. 2.5 Hierarchy of the sources of evidence in EBS based on McCulloch and Badenoch [24] and the University of Virginia, Health Sciences Library [25]
When reading the evidence, it is important not to lose sight of scientific rationality, so as to acquire best evidence for best patient outcomes. The concepts of information validity need to be rigorously assessed. These include:

- Bias
- Sample and study sizes
- Methodology
- Relevance

### 2.9 Managing the Increasing Volume of Evidence

In 2000, the non-profit medical research organisation OpenClinical produced a white paper entitled “The medical knowledge crisis and its solution through knowledge management” [29]. Here they recognised that “few busy doctors have the time to do the reading that is necessary and, even if they are assiduous in their reading, the imperfect human capacity to remember and apply knowledge in the right way at the right time and under all circumstances is clearly a critical limitation”.

As a result, they specified a number of fundamental points as follows:

- It is now humanly impossible for unaided health care professionals to possess all the knowledge needed to deliver medical care with the efficacy and safety made possible by current scientific knowledge.
- This can only get worse in the post-genomic era.
- A potential solution to the knowledge crisis is the adoption of rigorous methods and technologies for knowledge management.

In order to combat this “information overload”, a number of governmental bodies and medical groups propose knowledge management methods to enable clinicians to cope with this large volume of data [10, 22, 27]:

- Clinicians may need to become more super-specialised – to have an intimate knowledge of their own field.
- Multi-disciplinary teams, conference attendance and postgraduate teaching can help in the spreading of the most “important” evidence.
- Local, National and international guidelines can be an easy-to-reach source of best evidence.

- Increased use of free-to-use governmental and institutional internet “web-portals” will make best evidence easily accessible.
- Encouraged communication with interactive medical media and medical library facilities to facilitate evidence-based searching and practice.

To achieve universal application of these evidence-based knowledge management principles, there is a general requirement for the whole surgical fraternity to adopt an “evidence-based culture”. This requires the support and acceptance of evidence-based teaching and practice at all levels of surgery, whether in medical schools, national hospitals, private practice or academic surgical units. As a result, individual clinicians can be constantly informed with the most up-to-date knowledge, whilst also ensuring that future generations of surgeons will be satisfactorily educated to achieve successful outcomes using the best evidence.

### 2.10 Practising and Delivering the Evidence

The traditional practice of EBS was centred on individual clinicians taking responsibility for their own evidence-based practice. This would take place through required incentives to complete optional medical education accreditation for professional appraisals or awareness of either local or national guidelines. This optional adherence to evidence-based practice has led to a wide variability in its application [5].

It has recently been proposed that “Apart from health care professionals, the health care system itself and its influence on the delivery of care need to be considered” [5]. Measuring performance intrinsically allows the setting of a standard, which can then be compared against another standard, permitting a so-called system of “benchmarking” to be introduced. If the benchmarking measures are widely accepted, improved techniques in evaluating volume-output relationships and health inequality data can reveal important clinical outcome factors that can be improved upon.

Implementing these changes requires the involvement of senior leadership, health care management and hospital boards to advance and promote the evidence-based culture. This will facilitate innovative organizational design and structure whilst benefiting from information management and technology [30].
2.11 Surgical Modelling and Treatment Networks

When studying the surgical evidence, most systematic reviews and meta-analyses concentrate on studying one procedure in isolation or by comparing one treatment to another. This methodology yields an incomplete view of the treatments available to treat each condition, and does not deliver a holistic comparison of all the treatments available to treat each specific surgical disease [31].

The corpus of different treatments available for each condition can be considered to comprise a “treatment network”, where each treatment can be represented in a common frame of reference against all the others. Recently, mathematical techniques such as “multiple treatment” comparisons and “mixed treatment meta-analysis” have been introduced to compare the data for medical treatments and interventions within such networks [16, 29].

Applying these techniques to study networks has resulted in two conjectures:

1. Any representation of the evidence network needs to account for the fact that all the treatments have not been studied equally.
2. Any representation of the evidence network needs to account for the fact that there are varying amounts of published data for different treatment comparisons.

In order to create a visually representative model of comparing treatments that accounts for the last two conjectures, Salanti et al. [32] have devised a “geometry of the network”. Here, they specify that “network’s geometry may reflect the wider clinical context of the evidence and may be shaped by rational choices for treatment comparators or by specific biases”.

In order to create a visual representation of all studies for a specific disease, there needs to be consideration for two factors:

Diversity – The number of treatments for a specific condition.

Co-occurrence – the relative frequency where two specific treatments have been compared against each other.

Applying these factors, it is possible to represent all of the evidence for a specific condition (Fig. 2.6). Here, a line between two dots can represent a comparison of two treatments. The thicker the line, the larger the number of studies comparing the treatment (co-occurrence). The larger number of lines in a diagram implies increased diversity. An example would be the pharmacological treatment of LUTS – lower urinary symptoms (Fig. 2.6a). Here the centre of the image or “star” is placebo, to which all the treatments a–g are compared. The lines for a (α-Adrenoceptor antagonists) and b (5-α-Reductase inhibitors) are thicker than g (Antimuscarinics) and f (PDE5 inhibitors) as the former two are the subject of more studies as they are older drugs for this indication. Accordingly, lines g and f are in turn thicker than c, d and e, as these later

Fig. 2.6 (a) Treatment Network Geometry for the pharmacological treatment of LUTS – lower urinary symptoms. a: α-Adrenoceptor antagonists, b: 5-α-Reductase inhibitors, c: Luteinizing hormone releasing hormone antagonists, d: β-3-adrenoceptor antagonists, e: Vitamin D3 agonists, f: Antimuscarinics, g: PDE5 inhibitors, h: placebo. (b) Treatment Network Geometry for the laparoscopic surgical treatment of morbid obesity. a: vertical banded gastroplasty, b: gastric banding, c: sleeve gastrectomy, d: roux-en-y gastric bypass, e: duodeno-jejunal bypass, f: no surgery.
three are much newer drugs and have only a few studies considering their use.

Another example would be that for the laparoscopic surgical treatment of morbid obesity Fig. 2.6b. Here, one can see that there are many studies comparing a (vertical banded gastroplasty), b (gastric banding) and d (roux-en-y gastric bypass) to no surgery f. However, there are also many studies purely comparing b (gastric banding) and d (roux-en-y gastric bypass) alone in the absence of a comparison to f (no surgery), leading to a non-star shape. As c is a newer procedure, it is more commonly compared to established treatments such as b (gastric banding) and d (roux-en-y gastric bypass) and less so with f (no surgery), hence the thinner line of c–f. Being a much older procedure, e (duodenal-jejunal bypass) is not commonly performed laparoscopically, and hence, has not been extensively compared to the other laparoscopic procedures, explaining the thin line e, f.

The application of these geometric networks to surgery allows individuals to visualise in one diagram the overall treatment evidence for a particular condition. This empowers each individual surgeon to assess specific studies within the context of all known treatments for a condition. Furthermore, it can also allow for mathematical applications to place values on the strength on the levels of evidence for each treatment.

### 2.11.1 Surgical Thinking and Evidence Synthesis

As previously described, a good method of attaining good quality quantitative evidence for EBS is the application of meta-analysis and systematic reviews to integrate the results of high quality clinical trials. However, not all surgical evidence is in the format of high quality randomised trials, and some surgical questions may never be practical enough or ethically appropriate to obtain randomised controlled data. As a result, applying traditional methods of comparing trials by meta-analysis may not always be possible, and furthermore, publication of data based on these techniques alone can lead to a bias in the literature (focusing only on data that can only be accrued for RCTs).

In order to accommodate for this lack of data whilst also applying the concept of Best Evidence, a technique has been introduced known as “Evidence Synthesis”. Here, statistical models are employed to combine multiple sources of quantitative data from trials of heterogeneous quality and design (Fig. 2.7). Furthermore, these techniques can also allow for qualitative data to be included in these mathematical analyses. This technique, therefore, adds a new paradigm shift in the inclusion of traditional psychosocial and economic research to traditional trial evidence in order to allow for a totally holistic data analysis.

The role of evidence synthesis is increasingly applied in the assessment of health care outcomes and technology, and now has an expanding role in The National Health and Medical Research Council of Australia [33] and the United Kingdom’s National Institute for Health and Clinical Excellence [34].

Many of the recent advances of Evidence Synthesis in Health Care assessment have been as a result of the application of Bayesian statistical theory, where the mathematical techniques allow the supplementation and enhancement of conventional meta-analysis. Other techniques include Qualitative Comparative Analysis wherein qualitative data can be modelled into mathematical values to facilitate knowledge comparison and analysis. These methods account for the study quality in evidence synthesis, as they can incorporate a broader body of evidence to support decision-making, and therefore, successfully address many analytical problems in EBS. These include baseline risk effects, study heterogeneity and indirect comparisons.

### 2.11.2 Bayesian Techniques

The perceived current “gold standard” of evidence-based research is information in the form of Randomised Control Trials or Systematic reviews appraising them. These study designs, however, are based on a “frequentist school”, where the results are expressed as a probability value (p value) that is extracted from a model whereby an infinite number of probabilities can occur on a distribution with an unknown estimated effect value that can only be expressed with confidence intervals [35].

Another approach is the Bayesian one, where all the analysis work is on known data and a prior belief which yields a credible value near the sample mean. This is now being increasingly used in medicine and is defined as the “explicit quantitative use of external evidence in the design, monitoring, analysis, interpretation and reporting” of research.
In order to calculate a probability using Bayesian Statistics (Fig. 2.8), there are the following parameters [36]:

1. Prior distribution – the probability of a parameter based on previous experience and trial data
2. Likelihood – probability of a parameter based on data from the current research study or trial.
3. Posterior distribution – the updated probability of a parameter based on our observation and treatment of the data.

These techniques have proven to be particularly useful in [37]:

- Grouped meta-analysis (cross design synthesis)
- Cost-effectiveness studies
- Comprehensive decision modelling
- Decision analysis

### 2.11.3 Qualitative Comparative Analysis (QCA)

This method employs the use of truth tables to categorise qualitative data into mathematical values. This requires the setting of thresholds to classify a finding as either positive or negative (binary 1 or 0). Based on these thresholds, studies can be classified into scores and can be assessed by Boolean algebra [37]. An example is given in Table 2.1.

In this hypothetical set of manuscripts the Boolean equation follows that $D = A + B + C$. Thus, it can be seen that surgical errors can result from any or all of: poor communication, distractions in theatres and inexperienced operators.

### 2.12 Surgical Decision-Making and Clinical Judgement Analysis

The main reason to perform EBS is to improve the quality of care and outcome of our patients by modifying our surgical judgements and decisions. According to a well-known surgical aphorism, “a good surgeon knows how to operate; a better surgeon knows when to operate; the best surgeon knows when not to operate” [39]. Appropriate clinical judgement and decision-making skills are considered to be of paramount importance in surgery, and hence, in the UK, they have
recently been explicitly included in the Intercollegiate Surgical Curriculum Project [26].

Surgical judgement and decision-making can range from very well-defined levels, with relatively narrow range of options (e.g. to use one surgical forceps over another during an operation), to less well-defined situations in which surgeons need to consult their patients before reaching a decision (e.g. whether to offer surgery to a patient given the stage of his/her disease and lifestyle factors) [28, 36]. Regardless of the level of complexity of the situation, from a psychological perspective, optimal surgical judgment encompasses three components: Experience, Evidence and Inference (Fig. 2.9).

Surgeons make judgements and decisions on the basis of available information and their interpretation of it. The gathering and processing of the information are cognitive processes, which are open to influences from both our “cognitive architecture” and also the external environment (Fig. 2.10). Simply put, we examine our patients and gather relevant diagnostic information (e.g. blood tests, laboratory findings, etc.). Each one of these pieces of information is a “cue”, which we use to form a clinical judgement; this judgement will then lead us to make a decision (e.g. to treat or not, whether to offer a laparoscopic or open procedure). In the process of forming a judgement, these cues are weighted – although we are usually not consciously aware of this weighting process (unless we are dealing with a very difficult decision). Our final decision is driven by the weightings of the individual cues that we have considered and also the influences of internal cognitive factors (e.g. our inherent limitations in processing large quantities of information) and external environmental influences (e.g. the time we have to see a patient in clinic or in a ward round) [28].

Psychologists have developed models that explain how this integration of the various cues works. A model of particular relevance to surgery is that

**Table 2.1** Hypothetical truth table showing causes of surgical error

<table>
<thead>
<tr>
<th>Conditions (explanatory variable)</th>
<th>Surgical error (dependent variable)</th>
<th>Number of reports</th>
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<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
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A = poor communication; B = distractions in theatres; C = inexperienced operators. Table format based on [38]

![Bayesian statistics](image)
developed by Egon Brunswik and known as Social Judgement Theory – with its quantitative application, Clinical Judgement Analysis [40–43]. Social Judgement Theory treats surgical (or any other) judgement as a linear multiple regression model. Different cues are considered and assigned weights by the surgeon – thus, the relative importance for each cue can be algebraically estimated and surgeons can be classified into different subgroups, depending on the importance they assign to different cues: this reveals how different surgeons approach a clinical decision. This is important in EBS as it can allow judgements to be assessed before and after teaching and training in the adoption and application of best evidence.

Clinical Judgement Analysis has been used in a number of surgical studies. It has been used to clarify how demographic and lifestyle factors impact the prioritisation decision for patients due to have elective general surgery [44] or cardiac surgery [45], what clinical factors urological surgeons consider when deciding the treatment of prostate cancer [46] and how expert nephrologists diagnose non-end stage renal disease [47]. Importantly, this approach allows quantitative feedback to be provided to individual surgeons as a training intervention to improve their clinical decision-making [5, 23, 48]. This is done by assessing personal decisions and the breakdown of individual weights (i.e. importance) given to each information cue. These results can then provide feedback and be modified for each clinician to achieve results that are based on the best evidence.

2.13 Cost Effectiveness in Evidence-Based Surgery

It is becoming increasingly evident that although EBS can reveal the best treatments for a specific disease, the provision of these treatments may not be possible, particularly from a financial standpoint. In order to supply patients with the best care, both “best treatment” and “available funds” need to be considered. Achieving a
balance between these two factors can be complex and involves not only clinicians, but also health care management, economists and politicians.

Economic considerations have traditionally been poorly represented in the evidence-based literature, for example, a systematic review examining the cost effectiveness of using prognostic information to select women with breast cancer for adjuvant chemotherapy only revealed five published papers in the field. Health care costs are now of utmost importance in today’s complex financial markets. In the United States alone, medical care consumes more than 14% of the gross domestic product [49], which could increase to 17.7% by 2012 [50]. Despite the constant rise in new medical treatments, it is now widely recognised that “health interventions are not free, people are not infinitely rich, and the budgets of health care programmes are limited. For every dollar’s worth of health care that is consumed, a dollar will be paid. While these payments can be laundered, disguised or hidden, they will not go away [13]. In order to incorporate economic considerations in evidence-based guidelines, cost-effectiveness analyses (CEAs) are now being utilised and are gaining increased importance in medical guidelines at all levels (local, national, international).

CEAs can reveal the expected benefits, harms, and costs of adopting and translating a clinical recommendation into practice [51]. It is a tool that allows decisions to be made within the realistic constraints of health care budgets. This takes place through the expression of a cost-effective ratio where the differences in the cost between two interventions are divided by the difference of the health effects or outcomes of these interventions [52, 53].

\[ \frac{C_1 - C_2}{O_1 - O_2} \]

\( C = \text{Cost}, \ O = \text{Outcome} \)

The cost \( C \) is measured by:

\( C = \text{cost of intervention} + \text{cost induced by the intervention} - \text{costs averted by the intervention} \)

Outcomes \( O \) can be measured by:

- Life-years saved (LYS) = amount by which an intervention reduces or mortality or
- Quality-adjusted life years (QALY) = effect on an intervention on both loss and quality of life.

Cost-effectiveness analyses that use QALYs are termed cost-utility analyses (CUAs) and have become increasingly important as the incorporation of quality of life in the assessment better reflects clinical reality and clinical decision-making.

Other economic analyses applied to health services include cost-minimisation analyses and cost-benefit analyses (CBAs), although in contrast to CEA’s, they do not have the capacity to compare the value of cost compared to clinical outcomes [53].

CEA’s provide valuable information for developing and modifying health service interventions and preventative measures to obtain the best care with the best value. They can be used to compare the costs and benefits of various interventions for the same pathology or disease (for example colorectal screening by examining occult blood tests, barium enemas or colonoscopies).

Furthermore, they can clarify the cost-benefit of which intervention is appropriate for:

- Specific population subgroups (e.g. Off-Pump vs. On-Pump coronary artery bypass grafting in patients with renal dysfunction)
- Specific population age (breast screening by mammography between the age of 50–70)
- Various treatment frequencies and times (e.g. PAP testing for cervical neoplasia every 3 years)

The use of QALYs as an outcome measure in CUAs has shown particular benefits in accounting for patient preferences for some health conditions over others. For example, although numerous trials report the effectiveness of tamoxifen in improving morbidity and mortality in breast and endometrial cancer patients, its effects on perceived health status in these different conditions vary. CUAs allow for such variation and provide policymakers with data that reflect both financial suitability but importantly population needs and preference [53]. Arguments against the use of CEAs include:

- A historical lack of standardised CEAs making comparisons difficult
- A paucity of studies
- A lack of transparency in the complex models applied
- QALYs being non-intuitive
- Ethical concerns (for example is a year of life saved or QALY for a 70 year old equivalent to that for a 1 year old? Or the perception that CEAs can be used as tools for “rationing” in health care.)

Financial considerations are nevertheless inevitable, and there are a number of considerations that can allow
best use of CEAs in evidence-based practice. These include the following [54]:

- Consideration of resource use and not monetary values alone.
- Consideration of the specific context of an intervention and the resources needed.
- Applying a broad perspective, particularly at national and international levels.
- Consideration of the quality of evidence and the quantity of resource expenditure.
- Applying up-to-date economic models.

CEAs, therefore, are a powerful tool in selecting evidence-based interventions and protocols that are best suited to the budgets restraints of health care institutions, while also accommodating the preferences of both clinicians and patients. As a result, CEA scores can be classified by a league table which permits the selection and prioritisation of treatments either locally within a health care institution, or at a broader national or international level.

2.14 Surgical Training in Evidence-Based Techniques

In order to adhere to an evidence-based culture, training programmes in EBS are essential. When teaching this topic, it is important not only to teach the techniques of evidence searching (as above), but also to contextualise the whole process to make sense to the individual user at an individual institution. Principles of teaching these processes include the following [28]:

- Compiling a list of sources of evidence
- Identifying the influences on the decision-making and the role of evidence
- Applying appropriate levels of evidence base for decisions in context
- Discussion of the tactics on how to acquire evidence at an appropriate level
- Discussion of implementation strategies

To successfully fulfil all these steps, the teaching needs to be an interactive process. Ideally, it requires pairing of junior and senior clinicians together to allow mutual insight to be discerned from each others’ clinical experience. Furthermore, it is vital that a variety of “open-minded” teaching methods are applied to facilitate the learning process. These include brainstorming, role-playing and adoption of a variety of multimedia tools. In these situations, some individuals should be chosen to help lead the brainstorming and minute-keep the conclusions of each individual pair or group, so as to spread the knowledge to a wider teaching group [28].

Toedter et al. [55] have designed and implemented an EBS teaching schedule to enable all the residents in their programme to develop and refine their EBS skills in a context as close as possible to that in which they will use EBS in their clinical practice. To achieve this, they are given a clinical question (something they might very well be asked by an attending surgeon during rounds) and are asked to demonstrate their competence in finding the best available evidence to answer it.

They apply a multi-disciplinary collaborative approach to address “the four steps of EBS”, and each EBS group includes a resident or registrar (junior clinician), attending surgeon or consultant (senior clinician) and medical school or university librarian. In this context, the senior clinician would lead the formulation of an evidence-based question and also integrate the information in accordance with the best available evidence. The resident or registrar would act as a research coordinator to critically appraise the literature to find the best evidence, and the medical librarian would lead the focused search on the relevant literature. It was demonstrated that evidence-based performance of a resident was related to his or her ability to gather the best evidence in answer to a clinical question \( P = 0.011 \). However, it was also revealed that after additional training, the residents improved their evidence-based skills. It can be concluded that these skills can no longer be limited to academic surgeons, but are to encompass all surgeons universally. Evidence-based concepts will necessarily be required at all levels of surgical education; beginning at the formative years of medical school continued to the end of surgical practice.

2.15 Ethics

At a cursory level, EBS seems very straightforward from an ethical perspective; using “best evidence” is literally the optimum strategy to use for our patients
and applying anything less could be considered as suboptimal. However, with a more in-depth analysis, a number of ethical questions arise when studying the processes involved in EBS (Fig. 2.11).

Two broad concepts need to be addressed:

- What qualifies a surgical procedure or technique to have “sufficient” evidence for use?
- At what point of introducing a new procedure/technique are we protecting our patients or exposing them to an unknown risk?

To answer these questions, the fundamental principles of medical ethics [58, 59] need to be considered. These include beneficence, non-maleficence, autonomy, justice, dignity and truthfulness. Topics arising specifically in EBS [60, 61] (Fig. 2.11) cover issues in informed consent where patients need to be clearly aware of when an operation is for research, based on evidence or based purely on tradition. Furthermore, the reasons for the use of this operation by the responsible surgeon performing it need to be clearly identified. Whether the operation is experimental, new or well-practised, the risk benefit to the patient needs to be specified.

If the operation is selected on evidence-based grounds, then the level of evidence needs to be communicated to the patient in a way that he or she understands. Surgeons need to specify the research design of the evidence and discuss its appropriateness.

Both surgeons and patients have their own equipoise, and their awareness of surgical choice based on personal biases should be negated in favour of the best evidence and objectivity.

There also remains the issue of ethics in a healthcare world of limited finances and the challenges of distributive justice. What is the cost-effectiveness of each procedure? Should there be rationing in healthcare on evidence-based grounds? And how does one address the situation in which the best evidence alludes to an expensive treatment that cannot be afforded by some communities?

These considerations should be made by individual surgeons, and also by surgical institutions at both national and international levels. The concept of EBS is to ensure that each patient is treated along the grounds of best knowledge. Application of ethics to this evidence adds compassionate morals to the evidence-based decision-making, which in turn leads to the best possible humane care for patients.

2.16 Conclusion

EBS is no longer only about doing randomised control trials and for senior academic surgeons. It is for all surgeons, their colleagues and their patients. It works on the principles that best surgical practice is achieved through best surgical evidence. It is now inevitable and has the potential to address all the primary needs of our patient-oriented surgical practice, namely:

- Patient management
- Patient care
- Patient safety
- Patient outcomes
- Patient satisfaction

The steps required from deciding what evidence to find and how to implement changes to best reflect this evidence are illustrated in Fig. 2.12. Many of these steps include clear and logical questioning, dedication in
pursuit of excellence and ultimately a culture in which best-evidence is not a bonus, but rather a fundamental requirement. This cannot be done simply by individuals, but requires teamwork at all levels of health care, from local to national and international. Furthermore, EBS is not a one-way process, but requires reassessment, revision, repeated searches and constant updating to reflect the new advances in surgical evidence. As surgeons, it is not only our duty to contribute to the momentum of evidence-based practice, but actually a necessity for us to lead in many of these strategies. This requires universal training and re-training in evidence-based methods to reach a level of understanding that would place best-evidence at the heart of our surgical careers. For the vast majority of surgeons worldwide, the traditional concept of hand-hygiene before operating is now intuitive and “second nature” to them. For the next generation of surgeons, it would also be ideal to consider “best evidence” instinctively before coming to make any surgical decision.
References

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